

AGENDA

October 13, 2011 Circulatory System Devices Panel Cook Inc. for the Zilver-PTX Drug-Eluting Peripheral Stent Gaithersburg Hilton

Panel Chairperson Clyde Yancy, M.D.

Designated Federal Officer

James Swink

08:00	am	Call to Order Conflict of Interest and Deputization of the Voting Members Panel Introductions
08:15	am	Sponsor Presentation
09:30	am	Sponsor Q&A
10:00	am	Break
10:15	am	FDA Presentation
11:30	am	FDA Q & A
12:00	pm	Lunch
01:00	pm	Open Public Hearing*
02:00	pm	Panel Deliberations and FDA Questions
03:30	pm	Break
03:45	pm	Panel Deliberations and FDA Questions
05:00	pm	FDA and Sponsor Summations
05:30	pm	Panel Vote
06:00	pm	Adjournment

^{*} Open Public Hearing – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.